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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

DUE DATE:	—	
FORMALITIES:	CN	RR
PAT. OFF:	AK	
ON DB	12/6/06	
CASE NO:	PU0460-PC	

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PU0460-PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2005/000293 ↓	International filing date (day/month/year) 25-02-2005 ↓	Priority date (day/month/year) 27-02-2004
International Patent Classification (IPC) or national classification and IPC See Supplemental Box		
Applicant GE HEALTHCARE BIO-SCIENCES AB ET AL		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand 01-09-2005	Date of completion of this report 08-06-2006
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer Patrick Andersson/EÖ Telephone No. +46 8 782 25 00

Form PCT/IPEA/409 (cover sheet) (April 2005)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: **Cover sheet**

International patent classification (IPC)

B01D 15/18 (2006.01)

B01D 15/32 (2006.01)

B01D 15/36 (2006.01)

B01J 39/04 (2006.01)

C07K 16/06 (2006.01)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2005/000293

Box No. I Basis of the report

1. With regard to the language, this report is based on:



the international application in the language in which it was filed



a translation of the international application into _____, which is the language of a translation furnished for the purposes of:



international search (Rules 12.3(a) and 23.1(b))



publication of the international application (Rule 12.4(a))



international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:



the international application as originally filed/furnished



the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____



a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing (*specify*): _____



any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).



the description, pages _____



the claims, Nos. _____



the drawings, sheets/figs _____



the sequence listing (*specify*): _____



any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>4-5, 9-16, 18-22</u>	YES
	Claims	<u>1-3, 6-8, 17 and 23-25</u>	NO
Inventive step (IS)	Claims	_____	YES
	Claims	<u>1-25</u>	NO
Industrial applicability (IA)	Claims	<u>1-25</u>	YES
	Claims	_____	NO

2. Citations and explanations (Rule 70.7)

The following documents are considered relevant:

D1) Johansson B-L, "Preparation and characterization of prototypes for multimodal separation aimed for capture of positively charged biomolecules at high-salt conditions", 2003, vol 1016 page 35-49 Journal of Chromatography A.

D2) BLANK GS, ET AL.: "Expanded bed absorption in the purification of monoclonal antibodies: a comparison of process alternatives." 2001, vol. 10, pages 65-71 BIOSEPARATION,

D1 discloses a process for purifying antibodies using a multimodal separation material which is a cation-exchange resin with aromatic ring systems where the ring-forming atoms can be carbon, sulphur or oxygen, see table 2, figure 3 and the whole document. It is stated that the resin should be tested for capture proteins from different feedstocks.

Consequently, the subject matter of claims 1-3, 6-8, 15, 17 and 23-25 is previously known and therefore lacks novelty.

Document D1 is considered to represent the closest prior art. The invention according to claims 4-5, 9-12, 14, 16, 18-22 differs from the process in D1 in that it has an additional purification step thereby obtaining antibodies with higher purity.

Consequently, with the background of D1, the problem is to design a process that obtains antibodies with higher purity. It is well established in the art of protein purification in general, as well as for antibodies, to use an additional

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Box V

chromatography step in purification. Hence, a person skilled in the art would seriously consider additional chromatography steps when purifying antibodies with the resin of D1. Therefore, the invention according to claims 4-5, 9-12, 14, 16, 18-22 lacks an inventive step.

Claim 13 is directed to a process using a second chromatography step in a flow through manner. Such chromatography has been applied on immunoglobulins, see e.g. D2. Therefore, a person skilled in the art would include said method among the methods considered in the second step - see previous reasoning concerning claim 4 etc.

Therefore, the invention according to claim 13 lacks an inventive step.

Claims 1-25 are considered industrially applicable.